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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,428	09/03/1999	HANS-JUERGEN KUHR	BMD9813US	5380

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EXAMINER

NGO, LIEN M

ART UNIT PAPER NUMBER

3727

DATE MAILED: 06/19/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/389,428

Applicant(s)

KUHR ET AL.

Examiner

LIEN TM NGO

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-32 and 43-51 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-25, 27, 29, 30, 43, 46-48, 50 and 51 is/are rejected.
- 7) ☒ Claim(s) 26, 31, 32, 44, 45, and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. *Continued Examination Under 37 CFR 1.114*

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/9/03 has been entered.

3. Applicant's election without traverse of Species I (claims 22-27, 29-32 and 43-51) in Paper No. 28 is acknowledged.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: for example: the rejector "20a" (page 25, line 29). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 48 is objected to because of the following informalities: "the lancet device" should be --the lancing device--. Appropriate correction is required.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 22-25, 27, 29, 30, 43, 46, 48 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Raybin (3,244,317).

In regard to claims 22, 23, 25, and 43, Raybin discloses, in figs. 1-10, a system the is capable of collecting body fluid comprising a lancing device 15, a lancet magazine 1 storing a plurality of lancets 7 having sterile tip, a transport device (3 and 10) adapted to travel along a guide groove 11 within the lancet magazine to transport lancets, and opening 24 into which the lancing device can be inserted to remove an individual lancet from the lancet magazine (best seen in fig. 4). The lancets are arranged next to one another in pair-wise contact.

In regard to claim 24 and 27, the lancet magazine has an elongated, flat cuboid shape.

In regard to 29 and 30, the transport device is a manually operated slide 3 and a spring mechanism 10.

In regard to claim 46 and 48, the lancing device comprise a holding tongue 16 which is inserted into the opening to remove a lancet from the lancet magazine.

In regard to claim 51, each lancet comprises a pin 21.

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8. Claim 50 is rejected under 35 U.S.C. 102(e) as being anticipated by Nguyen et al. (5,829,589). Nguyen et al. disclose, in figs 3-5, a system comprising a lancing device 1 (delivery pen), a lancet magazine 35, a transport device 30 (the device 30 is capable rotate around the cover 20 when the cover 20 is held in place), and an opening 21 into which the lancing device can be inserted to remove an individual lancet from the lancet magazine. The system further comprising a plurality of lancets (needles) 100. The lancet comprising a lancet body 102 having opposed recesses (recesses between splines 110) and pins 101. Note that, Nguyen et al. delivery pen is capable of using as a lancing device to hold a needle body 100 which is capable of using as a lancet to pierce the skin of a person for collecting a body fluid.

The statement of intended use has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Nguyen device, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raybin in view of Abidin et al. (5,662,669).

Raybin does disclose the lancing device comprising a barb and an ejector.

Abidin et al. teach, in figs. 37-48, a lancing device comprising a barb 316, 312 and an ejector 311.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Raybin lancing device comprising a barb and an ejector, as taught by Abidin et al., in order to facilitate of removal of the lancet thereby voiding manual contact with the lancet.

Allowable Subject Matter

11. Claims 26, 31, 32, 44, 45 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 26 would be allowable because the prior art of the record, either alone or combination, does not disclose the lancet magazine having a second opening, in addition the opening into which the lancing device can be inserted, through which protective sheaths of the lancets can be ejected.

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Claims 31 and 32 would be allowable because the prior art of the record, either alone or combination, does not disclose one of the lancet magazine and lancing device having a pin and the other having a guide groove as claimed.

Claims 44 and 45 would be allowable because the prior art of the record, either alone or combination, does not disclose a protective sheath surrounding the lancet tip in the lancet magazine.

Claim 49 would be allowable because the prior art of the record, either alone or combination, does not disclose the opening of the lancet magazine having a substantially circular shape.

Response to Arguments

12. Applicant's arguments with respect to claims 22-25, 27, 29, 30, 46-48 and 51 have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments regarding to claim 50 have been fully considered but they are not persuasive.

Applicant argues that the Nguyen '589' container 30 can not be considered as a transport device because Nguyen only teach the cover 20 rotating with respect to container 30 and Nguyen does not mention anywhere the possibility of rotating container 30 to transport lancet. However that is not found convincing because although Nguyen teaches in col. 4, lines 15-15 and col 4, line

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13, cover 20 rotates with respect to container 30 or cover 20 is rotatably mounted on container 30, it is inherent that the container 30 is capable to rotate around the cover 20 when the cover 20 is held in place, and therefore, the container 30 is capable to perform as a transport device to move the needle 110 in the cavity 31 aligning to the slot or opening 21.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien Ngo whose telephone number is (703) 305-0294. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful. The examiner's supervisor, Lee Young, can be reached at (703)308-2572. The Group FAX number is (703) 305-3579.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-1148.



Lien Ngo

June 12, 2003